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Review of  
"A Method of Assessing the Health Risks Associated  
With Alternative Air Quality Standards for Ozone"  
(Draft dated July 1978)

A Report of the Subcommittee on Health Risk Assessment

September 1979

Science Advisory Board  
U.S. Environmental Protection Agency  
Washington, D.C. 20460

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## INTRODUCTION

The Subcommittee on Health Risk Assessment of the Science Advisory Board was established to advise the Agency on methodologies for assessing the health risks of various environmental pollutants. The Subcommittee was requested to review the methodology proposed by EPA's Office of Air Quality Planning and Standards (OAQPS), "A Method for Assessing the Health Risks Associated With Alternative Air Quality Standards For Ozone," draft dated July 1978. The Subcommittee reviewed the methodology at a public meeting on April 19 and 20, 1979, and provides the following report.

## CONCLUSIONS

I. The Office of Air Quality Planning and Standards is commended for recognizing the need for and undertaking the development of quantitative subjective decision aids for use in their assessment of the health risks of air pollutants.

II. The methodology developed by OAQPS is not ready for application in the process of establishing air quality standards.

## CONCLUSION I

The Office of Air Quality Planning and Standards is commended for recognizing the need for and undertaking the development of quantitative subjective decision aids for use in their assessment of the health risks of air pollutants.

This approach recognizes that when objective information is scarce, subjective judgments by scientific experts are often essential in making quantitative estimates of risks associated with environmental pollution. The approach organizes information on subjective judgments, identifies issues about which subjective opinions are made and makes the analytical process of assessing risks more explicit and open for public review. Properly done, probabilistic methodology will facilitate communication between scientific experts and decision makers.

## RECOMMENDATIONS

1. The Subcommittee urges the Agency to expand its efforts to develop and evaluate the use of judgmental probabilities in the process of establishing national air quality standards.

While EPA should strengthen its own in-house capability for assessing risks by developing a variety of methodologies, it should also seek proposals from a number of outside experts to allow formulation and comparison of alternative approaches. This should assure that the greatest number of potentially useful proposals are considered and provide an opportunity to compare the results of EPA's proposed methodology with other

approaches. However, the Subcommittee emphasizes that the application of such decision aids in the standard setting process must be avoided until these tools have been carefully refined and evaluated. As there is no practical way to verify conclusions which flow from the use of such methodology, its value to regulatory decision-making depends upon the extent to which the results are believed. Since no single formulation can be demonstrated to be "best," it is important that several be tried and compared and that an opportunity exist for the development of understanding and consensus. A clear understanding of the concept of a methodology and the procedures for applying it, the results of alternative analytical methodologies, and the opinions of experts about the validity and reliability of a given methodology is needed to establish confidence in the results. Although the developmental work may focus on the upcoming standard for carbon monoxide, no newly proposed methodology should be used in making the regulatory decision until credibility has been established.

2. Under no circumstances should use of such techniques become a replacement for the research needed to establish an objective data base for assessing health risks.

Because they are quantitative in nature and tend to produce quantitative graphical results, decision aids that use expert probabilistic judgments tend to "look scientific," but the techniques are not a substitute for scientific fact.

3. EPA should undertake or fund a major review of the experimental work addressing techniques and problems in eliciting quantitative expert opinions.

There is a body of literature which identifies important limitations and biases in people's abilities to make quantitative probabilistic judgments. This literature may not only assist in improving the elicitation of expert judgments but may also form a basis of legal objections to the use of quantitative decision aids. EPA's decisions on the use of methodologies involving judgmental probabilities should be made with a full appreciation of this literature.

## CONCLUSION II

The methodology developed by OAQPS is not ready for application in the process of establishing air quality standards.

A number of difficulties have been identified in the formulation:

1. The methodology is complex and proposes a new analytical procedure that is not adequately defined.
2. The mathematics and computer processing tend to obscure the fundamental modeling assumptions, making the analysis impenetrable to all but mathematical specialists. This is exactly what decision analysis techniques should not do.

3. The conceptual basis has not been clearly described, and standardized procedures for applying the methodology have not been developed.
4. Consideration of alternative approaches has not been documented and the results have not been compared with those of alternative approaches.

#### RECOMMENDATIONS

1. OAQPS should formulate a plan outlining how the Agency will (a) develop the proposed methodology, including standards and protocols for application, (b) consider alternative approaches, and (c) select and establish the credibility of the best methodology.
2. OAQPS should publish a short, easily understood description of the proposed methodology.

The paper should be written for a general audience and should not rely heavily on abstract statistical concepts. In addition, the authors should submit scientific papers on the methodology to critically edited peer review journals.

3. The encoding process and the method of dealing with differences in expert opinion need to be improved.

Meetings and interviews with experts are a critical part of the encoding process due to the risk of misunderstandings, errors and loss of credibility. The study on ozone is the only available example of how EPA would apply the proposed



methodology. The interviews in this example do not meet accepted standards. The authors should familiarize themselves with the available literature on the encoding procedure. Key concepts used in the interviews need to be explicitly defined. Differences in judgments should be reviewed with the experts to see if there is a true difference or a basis for consensus.

4. The expert committee's final deliberations in arriving at a probability distribution should be a matter of public record.
5. OAQPS described two approaches to developing a "dose-response" relationship. These formulations struck a number of members of the Subcommittee as awkward.

One approach used in the July 1978 report elicited opinions on the level of air pollution that would cause health effects in 1%, 5%, and 10% of the individuals in the most sensitive part of the population. The other approach fixes the level of air pollution and asks what fraction of the most sensitive population would suffer health effects at a given level of air pollution. EPA should work on developing the latter approach, as it provides the most useful information for the decision-maker.

6. Because of the considerable uncertainties on the air quality side of the model, this portion of the model should be reformulated so that expert subjective judgments can be used there as well.

The Subcommittee expressed concern about the appropriateness of a model which attempts to combine a variety of different expert judgments into a single summary finding. If this is to be done, careful discussion and justification of the procedures applied and the weightings used are required. Some members would prefer a methodology which pairs health effects and air quality judgments and allows the Administrator and his staff to examine and explore the full range of resulting outcomes through appropriate summary displays. No quantitative decision aid can replace the need for a deep technical understanding of the nature and sources of the uncertainties involved.

#### ADDITIONAL COMMENTS

The Subcommittee was asked to comment on several questions relevant to the use of the OAQPS methodology. Most of these have already been addressed. The following are comments on some of the questions not previously covered:

1. Are there Alternative Methodologies or Modifications?

It is apparent from the material presented at the meeting that there are a number of separate groups in EPA doing risk assessment. It is also apparent that these groups have little or no direct communication with each other. The Subcommittee

urges that EPA develop operational linkages between these groups. It is also suggested that these activities be reviewed and selectively presented to this Subcommittee for our input and advice as to which methodologies seem to hold the most promise, which might be replicated in other sections of EPA, and when to use which proposed method and under what conditions.

2. Under What Conditions Should the Methodology be Used or Not Used?

Encoding judgmental probabilities should be used only where it enhances communications between the scientific experts and the decision-makers. At one extreme, the uncertainty in the scientific data base may be so small that encoding expert opinion is not necessary. At the other extreme are cases in which the uncertainty in the data is so great that formal decision analysis approaches are not appropriate. Appropriate use lies between these extremes and will have to be judged on a case-by-case basis.

3. How Should Experts be Selected?

A principal criterion is that the user (EPA) and the public have confidence in the experts. There are no rigid rules, but the following guidelines may be helpful.

- a. The experts should encompass relevant disciplines and points of view within the scientific community. The goal should be to involve experts of recognized credibility.\*

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\* One member of the Subcommittee feels strongly that, insofar as practical, the experts should be free of personal interests or affiliations which might cast a reasonable suspicion about the neutrality of their judgments.

- b. The process of identifying and selecting experts should be explicit and open.
- c. Each expert should be willing publicly to acknowledge responsibility for the information and judgments he or she provides.
- d. Review and debate on the information and judgments should be encouraged both among the experts themselves and among their peers in the scientific community.

4. How Many Experts Should be Interviewed?

The Subcommittee suggests no specific number. The number will depend upon the complexity of the issues, the variety of scientific opinion, and the different kinds of expertise that are applicable. The experimental literature on eliciting quantitative expert opinion should be consulted, and EPA should consider undertaking sensitivity tests to determine how the results might vary with the number of experts.